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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Appeals and Interferences

In re the Application of

Inventors: Jose FEDIDA

Appln No.: 09/526,547

Filed: March 16, 2000

For: STRUCTURE OF A PROSTHESIS INTENDED TO BE IMPLANTED
IN A HUMAN OR ANIMAL PASSAGE AND PROSTHESIS WITH
SUCH A STRUCTURE

REPLY BRIEF

On Appeal From Group Art Unit 3731

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TABLE OF AUTHORITIES

<i>Hodosh v. Block Drug Co., Inc.</i> , 786 F.2d 1136, 229 USPQ 182 (Fed. Cir. 1986)	10
<i>In re Mills</i> , 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)	8
<i>In re Robertson</i> , 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999)	5
<i>In re Rouffet</i> , 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998)	10
<i>In re Royka</i> , 490 F.2d 981, 180 USPQ 580 (CCPA 1974)	7
<i>In re Vaeck</i> , 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)	10
Manual of Patent Examining Procedure, Eighth Edition, August 2001, §2131	4
Manual of Patent Examining Procedure, Eighth Edition, August 2001, §2141	10
Manual of Patent Examining Procedure, Eighth Edition, August 2001, §2112	5
<i>Verdegaal Bros. v. Union Oil Co. of California</i> , 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987)	4

ARGUMENT

This Reply Brief is a supplement to Appellant's Appeal Brief in that it addresses specific arguments presented in the Examiner's Answer. The arguments presented herein supplement those presented in the Appeal Brief.

Claims 18, 19, 22, 26, 27, 29, 30, 33, 37, and 38 stand rejected, under 35 USC §102(b), as being anticipated by or in the alternative, under 35 USC § 103(a), as being unpatentable over Goicoechea et al. (US 5,609,627). Claims 23, 28, 34, and 39 stand rejected, under 35 USC § 103(a), as being unpatentable over Goicoechea. Claims 21, 24, 25, 32, 35, and 36 stand rejected, under 35 USC § 103(a), as being unpatentable over Goicoechea in view of Lau et al. (US 5,873,906).

A. Rejection of Claims 18, 19, 22, 26, 27, 29, 30, 33, 37, and 38 as Being Anticipated by Goicoechea.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131.

Goicoechea fails to disclose the instant claimed links having a sole central portion and two loops, one loop at each of the ends of the central portion, whereby each of the two loops entraps a respective one of two corrugations that are to be linked together.

The Examiner's Answer proposes that Goicoechea *inherently* discloses that staple 99e is a "conventional staple used with a conventional stapler," such as that used in an office environment to hold sheets of paper together (Examiner's Answer, page 6, second and third paragraphs), i.e., a conventional U-shaped staple, used with a conventional office-environment stapler, including one single straight portion connecting two loops at both ends of the central portion in a linking position to hold sheets of paper (page 6, second to last paragraph).

However, the Examiner's Answer fails to establish inherency. To establish inherency, the Office must show, by cogent reasoning or objective evidence, that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. MPEP §2112; *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The Examiner's Examiner fails to meet this burden of proof.

Goicoechea discloses a bifurcated endoluminal prosthesis for use in a bifurcated blood vessel such as, for example, the infrarenal portion of a mammalian aortic artery where it bifurcates to the common iliac arteries (Goicoechea col. 1, lines 13-16). The Examiner's Answer acknowledges that such a prosthesis must be flexible for its deployment along a tortuous path of blood vessels (Examiner's Answer page 7, third paragraph, first sentence).

In light of Goicoechea's disclosure and the requirement of flexibility, it is clear that conventional staples used in a conventional office stapler are unsuitable for insertion into aortic arteries or are flexible enough for deployment through a tortuous path of blood vessels, contrary to the proposal in the Examiner's Answer. Moreover, there is nothing to support the allegation in the Examiner's Answer that Goicoechea uses a conventional office stapler to form the prosthesis that is inserted into the blood vessels.

Not only has the Examiner's Answer failed to show that Goicoechea's prosthesis necessarily uses conventional office staples to form the links connecting the hoops together, the intended use of the prosthesis makes it extremely improbable, if not impossible, that such is the case. It is similarly unlikely that Goicoechea's prosthesis is assembled with a conventional

office stapler. Therefore, the Examiner's Answer lacks the cogent reasoning or objective evidence required to prove that "[Goicoechea] must inherently indicate 99e as [a] conventional staple used with a conventional stapler," as proposed in the Examiner's Answer (Examiner's Answer page 6, second paragraph, second sentence).

Moreover, Goicoechea's Fig. 4F, which is enlarged on page 5 of the Examiner's Answer, illustrates a staple 99e enclosing two hoops 20 so as to hold them together. However, as may be seen clearly in the enlarged Fig. 4F, staple 99e forms a single loop having the shape of an oblong ellipse. Both of hoops 20 are enclosed within this single loop, as is evidenced by the illustrated overlap of the two hoops 20 at their arcuate vertices. If the two hoops were separately enclosed by opposing loops, then no overlap of the two hoops could occur in the perspective of Goicoechea's structure illustrated by Fig. 4F. And the Examiner's Answer is silent as to whether Goicoechea does disclose the feature. Instead, the Examiner's Answer only states that this is a well-known feature (Examiner's Answer page 8, first sentence).

In accordance with the above discussion, Appellant submits that Goicoechea fails to anticipate the structure defined by claim

18. Therefore, allowance of claim 18 and all claims dependent therefrom is warranted.

Independent claim 29 recites features similar to those discussed above in connection with the rejection of claim 18. For the reasons set forth in the Main Brief and the reasons set forth above with respect to the rejection of claim 18, Appellant submits that Goicoechea fails to disclose all of the features recited in claim 29. Therefore, allowance of claim 29 and all claims dependent therefrom is warranted.

B. Rejection of Claims 18, 19, 22, 26, 27, 29, 30, 33, 37, and 38 as Being Unpatentable over Goicoechea.

The Examiner's Answer proposes that the connection between a conventional staple and two objects/wires is well known to have a central portion between two loops holding two objects, such as wires (Examiner's Answer, sentence bridging pages 7 and 8).

However, the Examiner's Answer has not cited even one example of a staple that holds two objects, such as wires, together by holding each object in a separate loop of the staple. Instead, the Examiner's Answer cites a conventional office stapler that binds "objects/sheets of paper together" with a conventional staple (Examiner's Answer page 6, third paragraph).

The common configuration for binding paper together with a conventional office staple is one in which two or more sheets of paper are stacked such that their edges coincide. A central straight portion of the staple lies against the surface of the front sheet of paper, and the ends of the staple penetrate the stack of paper. Once the staple ends penetrate the stack of paper, an anvil of the stapler bends the staple ends so that they lay flat, or with a small arc, against the backside of the last sheet of paper in the stack.

The Office has failed to show an example, which existed at the time of the invention, of a connection between a staple and two wires whereby two loops of the staple, on its opposing ends, each hold a separate one of the two wires. Claim 18 recites that each of the links two loops entraps a respective one of the two corrugations. For the purpose of establishing a *prima facie* case of obviousness, an unsubstantiated statement that a structure is "well known" is not a substitute for the required showing that all claim features are taught or suggested by the applied art.

Applicant's specification discloses, in an exemplary but non-limiting embodiment of the invention, that the claimed feature improves the suppleness of the structure, firstly by preventing the two filaments bound by the links from rubbing together and secondly

by separating from one another the two parts of the structure associated with the two filaments (specification page 4, lines 15-23) .

Goicoechea neither suggests the claimed structure nor provides the motivation to make it. Instead, the Examiner's Answer proposes the motivation to make the claimed structure arises from the flexibility it would provide Goicoechea's device for easy deployment in a tortuous blood vessel (Examiner's Answer page 8, second paragraph) .

When applying 35 U.S.C. §103, the references must be viewed without the benefit of impermissible hindsight vision afforded by the Applicant's disclosure. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986); MPEP §2141. To prevent such use of impermissible hindsight, the prior art must provide a motivation to combine or modify the references that create the case of obviousness. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Stated another way, the prior art must provide the motivation to make the claimed combination or modification. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) .

Goicoechea does not describe providing flexibility or suppleness for the purpose of deploying a stent in a tortuous

passage. Moreover, Goicoechea does not recite any form of the root word "flex" in the disclosure.

However, Goicoechea does disclose making the stent resiliently compressible so that it can be implanted in an artery with the aid of a catheter. Specifically, Goicoechea discloses that the sinuous configuration of each turn 20 of the wire skeleton of stent 10 allows the prosthesis to be compressed resiliently radially inwards so that it can be received in a catheter for per cutaneous or cut down delivery to an intra luminal site in the infra renal section of the aortic artery (col. 10, lines 45-50). Goicoechea's structure does not rely on Appellant's claimed structure to provide its resilient compressibility and provides no suggestion to make the modification proposed in the Examiner's Answer.

Appellant respectfully submits that the motivation to modify Goicoechea's prosthesis to achieve the claimed structure may be found only through the impermissible hindsight afforded by the present application. The Examiner's Answer provides no evidentiary support for the conclusion that the claimed invention is suggested or motivated by the prior art. Absent some actual suggestion or motivation provided by the prior art for making the proposed modification, Goicoechea's disclosure and the proposed modification are not properly combinable to render the claimed invention

obvious. As a result, it is respectfully submitted that a *prima facie* case of obviousness has not been established.

Appellant further submits that the distinguishing features discussed above in connection with the anticipation rejections of claims 18 and 29 similarly patentably distinguish claims 18 and 29 from Goicoechea, with regard to the obviousness rejection. For brevity, that discussion is incorporated here by reference.

In accordance with the above discussion, Appellant submits that Goicoechea fails to disclose or suggest all of the claimed features and the benefits accruing from them. Additionally, the prior art fails to provide a motivation to modify Goicoechea's structure to achieve the claimed structure. Therefore, allowance of claims 18 and 29 and all claims dependent therefrom is warranted.

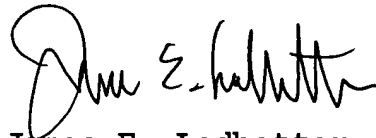
C. Rejection of Claims 21, 23-25, 28, 32, 34-36 and 39 as Being Unpatentable over Goicoechea or Goicoechea in View of Lau.

The rejections of claims 21, 23-25, 28, 32, 34-36 and 39 rely on the inherency argument presented in the Examiner's Answer to support the anticipation rejections of claims 18 and 29. For the same reasons Goicoechea fails to inherently disclose the cited features of claims 18 and 29, so too does it fail to inherently

disclose these features with respect to claims 21, 23-25, 28, 32, 34-36 and 39. Therefore, allowance of claims 21, 23-25, 28, 32, 34-36 and 39 is warranted.

In view of the law and facts stated herein and the Main Brief, it is respectfully submitted that all pending claims define patentable subject matter. Therefore, reversal of all outstanding grounds of the objections and rejections is respectfully solicited.

Respectfully submitted,



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